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Date: March 18, 2004 **Signature:** Jodi Jung

Name: Jodi Jung

SPECIFICATION

TO WHOM IT MAY CONCERN:

BE IT KNOWN, that We, Edgardo Costa Maianti, a resident of Mirandola, Italy, and a citizen of Italy; Nicola Ghelli, a resident of San Pietro in Casale, Italy, and a citizen of Italy; and Ivo Panzani, a resident of Mirandola, Italy, and a citizen of Italy, have invented certain new and useful improvements in:

DEVICE AND METHODS FOR PROCESSING BLOOD IN EXTRACORPOREAL CIRCULATION

of which the following is a specification:

DEVICE AND METHODS FOR PROCESSING BLOOD IN EXTRACORPOREAL CIRCULATION

Field of the Invention

The invention relates to a method and device for processing blood in extracorporeal circulation. Reference is made to co-pending application U.S. Serial No. _____ filed on even date herewith and entitled "Device and Method for Processing Blood in Extracorporeal Circulation" which is assigned to the assignee of the present invention and which is incorporated herein by reference in its entirety.

Background of the Invention

During certain surgical procedures it is necessary to establish a circuit for extracorporeal circulation of the blood of the patient. Such circuits may comprise devices such as blood reservoirs which may include a venous reservoir, that is meant to collect the blood that leaves the patient, and a cardiotomy reservoir for containing the blood drawn by recovery from the operating field, a pump for conveying blood in the circuit, a heat exchanger in which the blood encounters a heat exchange surface that maintains blood temperature at a desired value, an oxygenation device that is meant to transfer oxygen to the blood, and finally a filter known as an arterial filter, that is connected in the arterial line and is meant to retain any air bubbles that are present in the blood before the blood is returned to the patient.

All these devices can be present in the extracorporeal circuit as separate elements or they can be integrated in various combinations such as disclosed in co-pending U.S. Patent Application Serial No. 09/920,999 filed August 2, 2001 (U.S. Published Applicaiton No. 2002/0049401) which is assigned to the assignee of the present invention, and which is incorporated herein by reference in its entirety.

A need in this field exists, however, for a monolithic structure which integrates into a single package all of the various components necessary for use in an extracorporeal blood circuit used during heart bypass surgery or as an assist circuit during beating heart surgery.

Summary of the Invention

An object of the present invention is to provide a device that ensures optimum conditions of removal of the air contained in the device during priming and use and which is configured to allow an operator of the device to maintain visual contact with critical portions of the device during use so that the operator can take corrective action when a problem situation is observed.

This object and other objects that will become better apparent hereinafter are achieved by a device for treating blood in extracorporeal circulation that comprises an integrated structure that includes a venous reservoir, a cardiotomy reservoir, a centrifugal blood pump, an oxygenator, a heat exchanger and an arterial blood filter, all of which are inter connected by means of various tubing lines and/or ducts. The integrated structure forms a complete system which includes all of the components required in an extracorporeal blood circuit used during heart bypass surgery or used to assist the heart during beating heart surgery. The integrated structure is configured to be shipped to a user as a completely assembled and interconnected system or alternatively, to more efficiently use packaging space some minimal assembly might be required by the user.

The integrated structure includes a centrifugal pump provided with a transparent enclosure that is connected, by means of an inlet duct, to the outlet of the venous reservoir. The inlet of the venous reservoir is connected to a venous line for conveying the blood from a patient. The transparent enclosure of the centrifugal pump is connected to the portion of the unitary structure that comprises the heat exchanger and oxygenator. The centrifugal pump may be a standard component which connects to the structure in a manner known in the art. Usually the centrifugal pump will be connected prior to packaging so that

it is shipped and is received by the user as part of the monolithic structure although it could be shipped unconnected from the structure and connected by the user after receipt. That portion of the unitary structure comprising the oxygenator/heat exchanger has an inlet connected to receive blood from the centrifugal blood pump and also supports monolithically, at a peripheral region, the arterial filter. The arterial filter has an inlet connected to receive blood from an outlet of the oxygenator/heat exchanger. The arterial filter has an outlet connected to an arterial line for return of the blood to the patient.

In one embodiment the invention comprises an integrated device for oxygenating and filtering blood flowing through an extracorporeal blood circuit. The integrated device comprises a blood reservoir having an inlet for receiving venous blood and an outlet for supplying venous blood. The device includes a blood pump having an inlet connected to receive blood from the outlet of the blood reservoir and an outlet connected to a blood inlet of a heat exchanger. The heat exchanger has a blood outlet for supplying temperature controlled venous blood to the inlet of an oxygenator. The oxygenator has an outlet for supplying oxygenated blood to the inlet of an arterial blood filter. The arterial blood filter has an outlet adapted for connection to an arterial line for return of oxygenated blood to the patient. The integrated device includes a monolithic housing having a first portion for defining the blood reservoir, a second portion for defining the blood pump, a third portion for defining the heat exchanger, a fourth portion for defining the oxygenator and a fifth portion for defining the arterial blood filter.

The blood pump may comprise a centrifugal pump that is positioned within the monolithic housing such that an axis of the centrifugal pump is horizontal. The blood reservoir may comprise a combined venous reservoir and cardiotomy reservoir. Further, the monolithic housing of the integrated device may comprise connection means which allows removable connection of the first portion or the second portion of the housing.

In another embodiment the invention comprises a system for establishing an extracorporeal blood circuit. The system includes a blood reservoir, a blood pump, a heat exchanger, an oxygenator, an arterial blood filter and a housing for incorporating and interconnecting the blood reservoir, the blood pump, the heat exchanger, the oxygenator, and the arterial blood filter into a monolithic structure. The housing has an inlet for receiving venous blood from a patient and supplying the venous blood to the blood reservoir and an outlet for supplying oxygenated blood from the arterial blood filter to a patient.

The blood pump may comprise a centrifugal pump which is positioned within the housing such that an axis of the pump is horizontal. The blood reservoir may comprise a combined venous reservoir and cardiotomy reservoir. Further, the housing may comprise connection means for allowing removable connection of the blood reservoir or the centrifugal blood pump.

Brief Description of the Drawings

Further characteristics and advantages will become better apparent from the description of two embodiments of the invention, illustrated by way of nonlimiting example in the accompanying drawings.

Figure 1 is a longitudinal sectional view of the invention.

Figure 2 is another longitudinal sectional view of the invention according to a different embodiment of the venous reservoir.

Brief Description of the Preferred Embodiments

With reference to FIG. 1, the reference numeral 1 generally designates the device according to the invention, which comprises various components which have been integrated into a unitary or monolithic structure. These components are interconnected by various tubing lines or ducts to establish a blood flow path through the unitary structure according to the arrows shown in the figures and which will be described in detail, hereafter.

The unitary structure includes a venous reservoir 2, which is provided with an input connector 2a for connection to a venous line for receiving blood from the patient. Blood received from the patient through connector 2a passes through a filter 2b before it reaches venous reservoir 2. A cardiotomy reservoir 2c is contained within venous reservoir 2 and is connected receive blood recovered from the operating field through an inlet connector 2d. Blood received through inlet connector 2d passes through a filter 2e before it reaches venous reservoir 2.

An outlet connector 2f of venous reservoir 2 is connected at one end of duct 3. The other end of duct 3 is connected to an inlet of centrifugal pump 4. Centrifugal pump 4 has a transparent enclosure which defines an outlet connector 4b which is connected to delivery duct 4a, connected to provide blood from centrifugal pump 4 to an inlet connector 5a of heat exchanger 5. Heat exchanger 5 is provided with an outlet connector 5b that is configured to convey the blood to inlet 6a of oxygenator 6.

From the outlet 6b of the oxygenator 6, the blood reaches arterial filter 7, which is provided with an outlet connector 7a for connection to an arterial line for the return of the blood to the patient.

The transparent enclosure of the centrifugal pump 4 is connected monolithically to the end face of the structure that comprises the heat exchanger 5 and the oxygenator 6. Centrifugal pump 4 is oriented so that the pump axis is horizontal and outlet connector 4b is positioned at the top of the pump. This arrangement is beneficial for several reasons. First, it essentially ensures the complete removal of any air contained in the pump during its filling since any air bubbles in the device will rise because of their buoyancy and be expelled through the outlet connector at the top of the pump. Second, since the axis of the centrifugal pump is horizontal the entire rotor and pump chamber are visible to the operator through the transparent enclosure. This allows the operator to visually locate any air bubbles which may pass into or through the pump and to take appropriate corrective action in response thereto.

Furthermore, the ease with which the device may be set up and its operating convenience are both enhanced by the fact that the venous reservoir 2 is removably connected to a pedestal 8 that protrudes from that portion of the unitary structure that comprises the heat exchanger and the oxygenator by virtue of snap-acting means. This allows the venous reservoir/cardioplegia reservoir to be constructed as a first module of the system and the oxygenator/heat exchanger/arterial filter/pump to be constructed as a second module of the system. These two modules can be detached during shipment to conserve package space and assembled by the user by snap fitting the modules together during set up. Alternatively, they can be shipped completely assembled.

The embodiment shown in Figure 2 differs from the one described above only in that rigid or hard shell venous reservoir 2 is replaced by a flexible bag 9. Bag 9 is connected to a support 10 that extends from the structure that comprises the heat exchanger and the oxygenator and is provided with an inlet connector 9a for connection to a venous blood inlet line and with an outlet connector 9b that is connected to the inlet of pump 4 through duct 3.

The device of the present invention may be used as a fast, efficient and convenient alterative to the use of various individual components in a traditional extracorporeal blood circuit. Since the structure of the device incorporates these various individual components into a preconnected monolithic structure it can be set up and ready for use very quickly. Further, the present invention is advantageous for use in beating heart surgery for several reasons. First, since part of the blood is diverted into an extracorporeal circuit the heart has less blood to pump and therefore beats less making it easier for the surgeon to work on the heart. Second, in cases where it is necessary to change to full bypass during the surgery the monolithic device of the present invention includes an oxygenator and other components which provide the capacity and function necessary to accommodate the change. The present invention also includes methods of using the device to process blood during heart bypass or beating heart surgery.

It should be understood that the embodiments disclosed herein represent presently preferred embodiments of the invention. Various modifications and additions may be made to these embodiments without departing from the spirit and scope of the invention.